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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/857,943      | 06/12/2001  | Yoshio Hata          | 2001-0700A          | 2503             |

513 7590 07/25/2003

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EXAMINER

HAMPTON HIGHTOWER, PATRICIA

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/857,943

Applicant(s)

HATA ET AL.

Examiner

Patricia Hightower

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4/30/03; 12/30/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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***Information Disclosure Statement***

The information disclosure statement filed December 30, 2002 has been considered and has been made of record.

***Response to Amendment***

The amendment filed April 30, 2003 is acknowledged; in view of the applicant's response, the rejection of claims 10-18 as anticipated by Takeda Chemical Ind. (EPO 668 073 A2) has been withdrawn the polymer has no free terminal carboxyl group at the gamma end of the polymer chain nor does the reference teach a process of producing a biodegradable polymer having a free carboxyl group at the gamma end.

However, the claims 1-18 are subject to a new ground of rejection under 35 USC

102(b) as anticipated by EPO 601 799 A1 (newly cited and of record).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are newly rejected under 35 U.S.C. 102(b) as being anticipated by EP0 601 799A1 to Takeda et al (newly cited and of record).

EP0 601 799A1 to Takeda et al (newly cited and of record) discloses a sustained release preparation comprising a physiologically active peptide denoted by the formula (I) wherein Q in the denoted structural formula represents a salt thereof and a biodegradable polymer having a terminal carboxyl group; wherein the sustained release

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preparation shows a constant release of the peptide over a long time without an initial burst; the biodegradable polymer is a mixture of (A) a copolymer of glycolic acid and a hydroxycarboxylic acid of the formula (II), R represents an alkyl group of C<sub>2-8</sub> atoms and (B) represents a polylactic acid; which anticipates the claimed invention. See abstract; pages 3, 9, 11, 12, the examples, page 17, lines 108; claims 1-5, 15, 20-25.

Claims 1-13 are newly rejected under 35 U.S.C. 102(b) as being anticipated by EP1 197 208 A1 (newly cited and of record).

EP1 197 208 A1 (newly cited and of record) discloses sustained release compositions containing a physiologically active substance or its salt, hydroxy-naphthoic acid or its salt and a lactic acid-glycolic polymer or its salt and a lactic acid-glycolic polymer or its salt, wherein the product of the weight-average molecular weight of the lactic acid-glycolic acid polymer by the amount ( $\mu\text{mol}$ ) of the terminal carboxyl group per unit mass (g) of lactic acid-glycolic acid polymer is from 1,200,000 to 3,000,000 (inclusive) and their production; medicaments containing these sustained release compositions; which anticipates the claimed invention. See abstract; claims 1-3, 11; paragraphs (002), (0013)- (0016), (0026), (0039) – (0052).

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

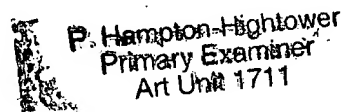
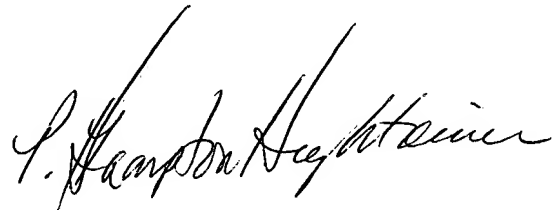
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Hightower whose telephone number is (703) 308-2434. The examiner can normally be reached on M-F from 9:30 A.M. - 6:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

P. Hightower/mn  
July 23, 2003



P. Hampton-Hightower  
Primary Examiner  
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